

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing (day/month/year) **See form PCT/ISA/210**

Applicant's or agent's file reference

P329905PC-La

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/DE2005/000589

International filing date (day/month/year)

29.03.2005

Priority date (day/month/year)

28.03.2004

International Patent Classification (IPC) or both national classification and IPC

A61K9/127

Applicant

NOVOSOM AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/EP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/DE2005/000589

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language
_____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format
☐ in computer readable form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
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International application No.

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims		YES
	Claims	1-45	NO
Inventive step (IS)	Claims		YES
	Claims	1-45	NO
Industrial applicability (IA)	Claims	1-45	YES
	Claims		NO

2. Citations and explanations:

Reference is made to the following documents:

- D1: WO 03/070735 A (NOVOSOM AG; ESSLER, FRANK; PANZNER, STEFFEN; ENDERT, GEROLT) 28 August 2003 (2003-08-28)
- D2: WO 02/066012 A (NOVOSOM AG; PANZNER, STEFFEN; FANKHAENEL, STEFAN; ESSLER, FRANK; PANZN) 29 August 2002 (2002-08-29)
- D3: BUDKER V ET AL: "PH-SENSITIVE, CATIONIC LIPOSOMES: A NEW SYNTHETIC VIRUS-LIKE VECTOR" BIO/TECHNOLOGY, NATURE PUBLISHING CO. NEW YORK, US vol. 14, June 1996 (1996-06), pages 760-764, XP002937150 ISSN: 0733-222X

The present application describes amphoteric liposomal formulations suitable for the intracellular delivery of oligonucleotides.

1. Novelty

The present application fails to meet the requirements of PCT Article 33(1) because the subject matter of claims 1-45 are not novel (PCT Article 33(2)).

Documents **D1 and D2** both disclose (reference passages, see ISR) amphoteric liposomes, suitable for delivering oligonucleotides and DNA/RNA, and the production

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Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

thereof. Furthermore, the aforementioned liposomes are made up of the same or at least very similar compositions as the liposomes of the present application.

Document **D3** describes cationic liposomes to be used as virus vectors and anticipates the novelty of claim 1 of the present application.

2. Inventive step

The present application fails to meet the requirements of PCT Article 33(1) because the subject matter of claims 1-45 does not involve an inventive step (PCT Article 33(3)).

Should the applicant be able to dispel the above-mentioned objections to novelty, he should also simultaneously correct the relevance of documents **D1-D3** with regard to inventive step and existing objections.

3. Industrial applicability

Claims 1-45 of the present application are considered industrially applicable.

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Box No. 1

Basis of this opinion

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